

CERAMENT G as Part of the Surgical Treatment of Osteomyelitis in a Single-Stage Procedure

NCT06555848

Status RECRUITING
Sponsor BONESUPPORT AB
Enrollment 128 participants

Key Eligibility Criteria

Inclusion (6)

- Patients receiving CERAMENT G subsequent to surgical excision of osteomyelitis, with Cierny-Mader classification grades III or IV, who require dead-space management of a bone defect following surgical debridement and excision of infection.
 - Symptoms for a minimum of six months with clinical and radiological features accompanied by at least one of the following:
 - the presence of a sinus
 - the presence of an abscess or intra-operative pus
 - the presence of positive supportive histology
- ... and 1 more (see full listing online)

Exclusion (7)

- The subject will be excluded from the study if:
 - Skeletal immaturity, defined as pre-operative/ screening radiology with evidence of incompletely fused physes. (determined by their previous x-rays which are taken as part of their admission, unrelated to the study)
 - Those unable to give informed consent for inclusion in the trial, or those not willing to be included
 - A known allergy or reaction to gentamicin or calcium sulfate
 - Treatment with a combination of different antibiotic-eluting bone graft substitutes
- ... and 2 more (see full listing online)

Locations (1 total)

Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, MHS, Oxford, United Kingdom